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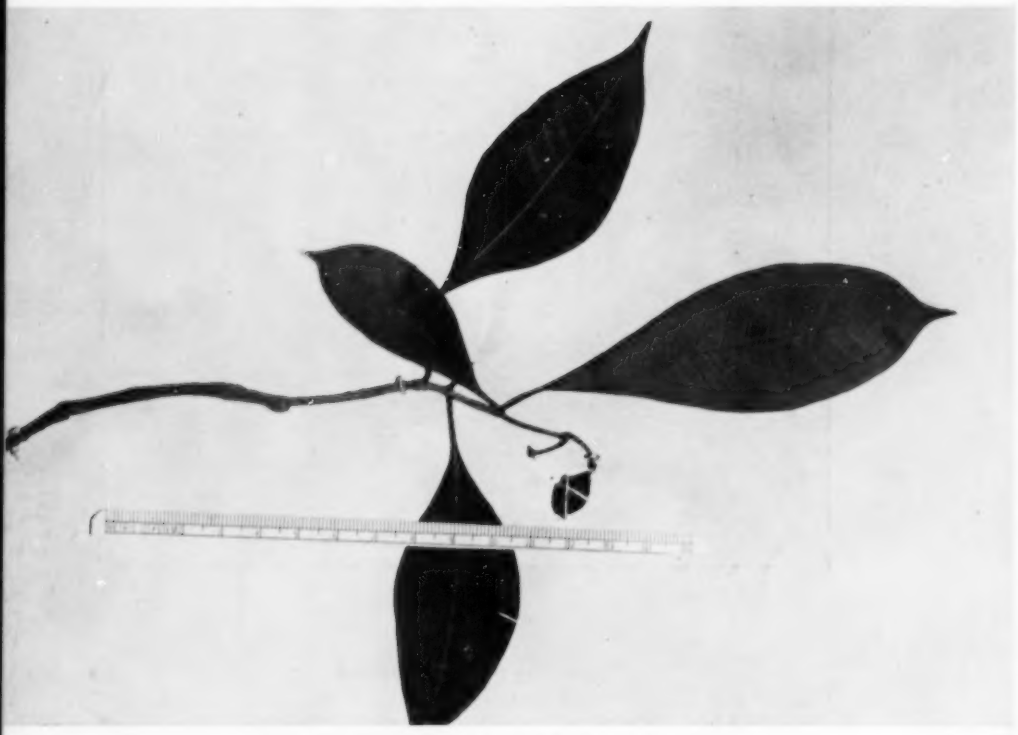

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American Journal of Pharmacy

Published monthly by the Philadelphia College of Pharmacy and Science
43d Street, Kingsessing and Woodland Avenues, Philadelphia 4, Pa.

Annual Subscription $4.00 — Foreign Postage, 25 Cents Extra
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Since 1825



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Vol. 128 NOVEMBER 1956 No. 11


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# E D I T O R I A L

## THE RESTRICTIVE SALES CONTROVERSY

THE so-called restrictive sales controversy is named by language which is ill-chosen. The term itself implies that someone is attempting to prevent the public from buying certain drugs which it needs for the self-treatment of relatively minor diseases or ailments. Neither side of the controversy wishes to do this, for the sale of home remedies is as much a vital part of the professional activities of the pharmacist as it is in the economic interest of the proprietary manufacturers.

That this controversy has done great harm to both sides is hardly debatable for it surely has not helped the sale of products which are involved in court litigation and it has not helped the professional prestige of pharmacy to hear those representing the proprietary interests make the pharmacist out to be something closely akin to a rapacious scoundrel who has no concern whatsoever for the public welfare. The truth, of course, is that both sides are guilty of considerable exaggeration of the inherent evils of the other and, like all participants in a heated argument, they have not used complete objectivity in describing the derelictions of their opponent. Those who have pointed out the need to end this controversy are on solid ground for its continuation is not something toward which any of us can look with great satisfaction. On the other hand, what is the nature of the so-called "compromise" which is extended by the proprietary interests? The terms of the compromise when boiled down into simple language mean capitulation on the part of organized pharmacy. This is not likely to happen and, in fact, it would be disgraceful, should it happen.

Whether the proprietary interests believe it or not, that which motivates pharmacists to oppose the sale of home remedies in all types of retail outlets is not simply economic self-interest. This, indeed, makes a very good argument in court but it is infuriating to those who have spent a number of years of hard work in gaining professional competence to hear their motives so impugned. Do the

proprietary interests really believe that all pharmacists are completely lacking in concern for the welfare of those in the community whom they serve?

It is tragic that, in this great government of ours which by legislative and executive action readily controls many of the day-to-day and even personal activities of its citizens, there is not some agency which will look at this controversy in the light of simple logic and on its merits.

The position taken by the proprietary group is that, since certain over-the-counter drugs are sold in some pharmacies without professional supervision, it follows that no professional supervision is needed and there is no reason why such products cannot be sold at any time in any type of retail store. The lack of logic in this stand is that they are attempting to justify an evil by citing a similar evil. Such an error in logic should not be permitted to confuse the issue. The simple question which must be answered in order to reach some decision in this case is whether the pharmacist, by his professional training, is better qualified to sell such products. The answer to this is inescapable. Who, other than the pharmacist, can really interpret to the uneducated, to the emotionally disturbed, to those who cannot see well enough to read, to those who do not read English, and even to those who wish further information those data and directions which are on the label. And suppose some point arises concerning the proper use of a drug which is not covered by the label, can the professionally untrained answer such a query?

Pharmacists are well aware of the problems which frequently arise in the proper sale of even the most simple and seemingly harmless drugs. As professional men and women, they can do little else but take a firm stand against a distributive system which would all but eliminate the availability of professional guidance when needed. In contrast, the proprietary manufacturers are motivated solely by a desire to expand their number of outlets and thereby increase sales. It is true that the products they sell are very useful drugs and are the kind of remedies that the public can use under proper conditions with great satisfaction and relief of pain.

We should like to suggest a real compromise between the warring parties and one by which the proprietary people would recognize the value of professional distribution of their products and try to encourage it. Organized pharmacy might then be willing to make certain concessions that would accommodate those who were not in a

position to purchase these products with professional guidance by reason of geographical considerations or other local conditions. The alternative to such a compromise is continued warfare. This could lead someday to some very serious pressure against certain manufacturers and even their ethical affiliates. The stragetic position of retail pharmacy in its ability to greatly influence the well-being or economic death of a manufacturer should not be overlooked. We sincerely hope that relations do not deteriorate until this is the eventual result.

L. F. Tice

# A PHARMACOGNOSTIC STUDY OF RAUWOLFIA DECURVA HOOK

By Chand K. Atal and Arthur E. Schwarting *

SINCE the isolation of Reserpine (1) from *Rauwolfia serpentina* and its subsequent use as a sedative and hypotensive agent, a widespread interest has been shown in the other species of the genus with a view to find alternative sources of reserpine and other alkaloids. As a consequence reserpine has been isolated from *R. canescens* (2), *R. heterophylla* (3) and *R. vomitoria* (4). A number of other species of Rauwolfia are being imported as substitutes or adulterants necessitating thorough pharmacognostic characterization of the genus.

Wallis and Rohtagi (5) have made a detailed pharmacognostic investigation of *R. serpentina*. More recently *R. serpentina, R. canescens, R. micrantha, R. densiflora* and *R. perakensis* have been described by Youngken (6, 7, 8). *R. perakensis* has also been the subject of a paper by Wan (9). Cantoria (10) and Youngken have recorded pharmacognostic observations on *R. vomitoria*.

*R. decurva* Hook, the subject of this paper, is an Indian species growing in an area where other commercially used species are collected and offers a possibility for its use as an adulterant or substitute.

## Materials and Methods

The material, supplied us through the courtesy of Dr. P. N. Mehra, Professor of Pharmacognosy, Punjab University, India, consisted of a mounted authenticated herbarium specimen of the plant (Fig. 1) and three lots of dried roots of varying diameters (Fig. 2). For histological examination, roots were softened by prolonged soaking in water and were sectioned on a sliding microtome. More specimens were prepared by embedding in paraffin, after preliminary treatment with 25 percent hydrofluoric acid for a week, and sectioned on a rotary microtome. Equal volumes of 10 percent solution of chromic acid and nitric acid was used for macerations.

## Plant and Root Description

The plant (11) is a stout shrub up to 2 meters in height. Leaves, in crowded whorls mostly at the tips, are oblanceolate, acuminate, 2.5-

* University of Connecticut, School of Pharmacy, Storrs.

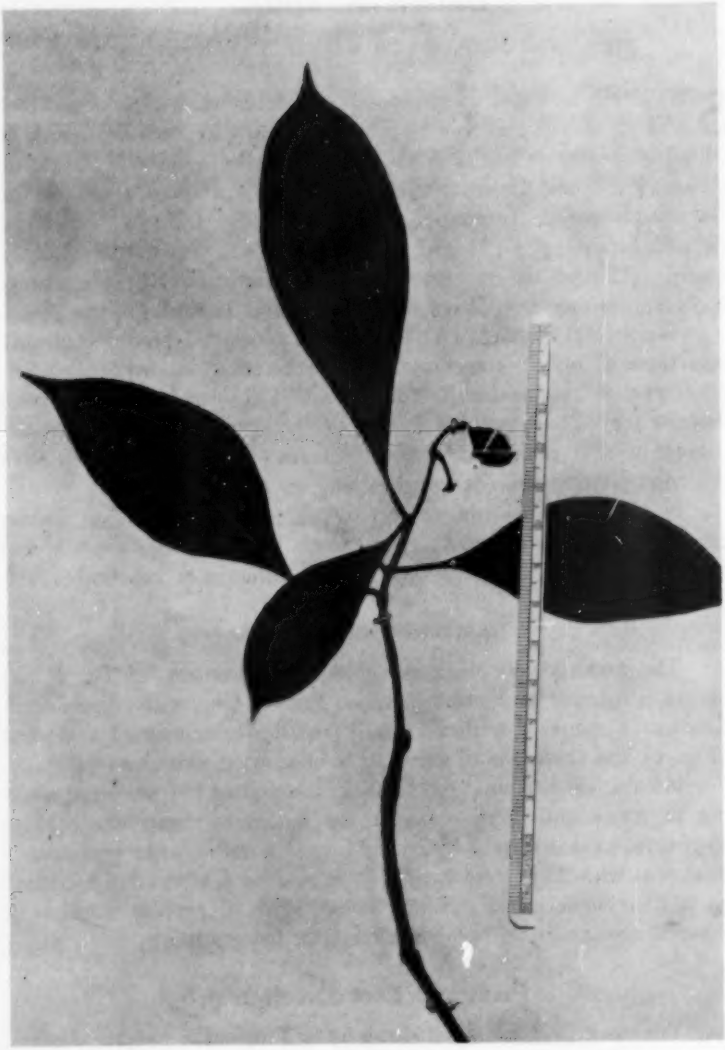

FIGURE 1

*Rauwolfia decurva* Hook. Plant showing leaves and fruit.

3.75 by 0.8-1.6 cm. Short, 2-6 flowered cymes, peduncle 1.25-2.5 cm. decurved. Flowers 0.8 cm., white to pink. Calyx lobes lanceolate, half the length of corolla tube. Corolla lobes rounded, as long as the tube. Fruit a drupe, 0.6 cm.

The root occurs as cylindrical or tapering transversely cut pieces (Fig. 2) up to 20 cm. long and varying in diameter from 0.3 to 5 cm. The thicker pieces occasionally show a broad root stock and also lateral branching. The comparatively thinner roots are unbranched straight or tortuous and gradually tapering. The cork is dirty yellow, velvety, and sloughs off easily. The surface shows deep longitudinal fissures and occasional transverse cracks. These cracks and fissures are more prominent on thicker roots. Certain thin roots show an almost smooth cork. The thick roots are hard and unbreakable while thinner roots show a short splintry, powdery facture. The cut transverse surface shows an extremely compact pale white wood. The bark in younger roots occupies more than one-third of the total diameter of the roots while in thicker roots the relative proportion of phloem becomes less. The root possesses a bitter taste and indistinct odor.

The cork of older roots shows stratification which, however, is not as distinct as in *R. serpentina, R. desiflora, R. micrantha* and *R.*

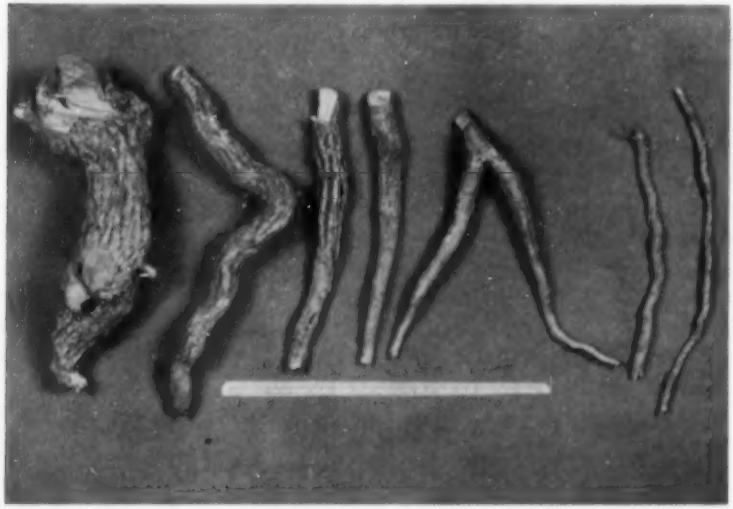

FIGURE 2
Dried roots of *R. decurva* Hook.

*perakensis* described by other authors (5, 6, 7, 8). There are two to three wide bands of radially broad cork cells (Fig. 3) which alternate with narrow bands composed of radially compressed cells. Each broad band is composed of 7-14 layers of rectangular to irregularly polygonal cells measuring 35-100 microns radially and 35-75 microns tangentially. The narrow band is composed of 2-3 layers of rectangular tangentially elongated to compressed cells measuring 35-75 microns tangentially and 7-15 microns radially. The cork cells show a polygonal outline in tangential section or when observed in the powdered drug and give a strong test for lignin.

The cork cambium is present as poorly defined 2-3 layers of rectangular radially narrow cells. In younger roots the secondary cortex is poorly developed being composed of 2-3 layers of parenchyma cells. In the older roots it is composed of 10-20 layers of thin walled cells which show tangential elongation. These cells measure 40-130 microns tangentially and 15-35 microns radially. The cortex cells are filled with starch grains, single or 2-5 compound, circular to planoconvex to polygonal in outline with a dot shaped or radiate central hilum. They vary in diameter from 2-7 microns. Cortical fibers, abundant in older roots (Figs. 3, 5, 6) occur singly or occasionally in pairs. In transverse section they appear as stone cells showing extreme variation in the thickness of the wall and size of the lumen. Their true form is revealed in a macerated preparation where (Figs. 5, 6) they appear as irregular spindle shaped fibers tapering acutely or obtusely. Rarely they assume a stone cell like form. They are 700-1050 microns long, 60-95 microns broad. Their walls measure 7-35 microns in thickness and the lumen may be almost obliterated to 90 microns in diameter.

Phloem is present as phloem strands separated by phloem rays of isodiametric cells. The rays are 1-3 cells wide. The phloem strands are composed of sieve tubes, companion cells and phloem parenchyma frequently containing prisms of calcium oxalate. In a longitudinal section these crystals occur as crystal fibers. Phloem parenchyma and the phloem ray cells are filled with starch. Cambium is present as 2-3 layers of radially narrow cells.

Xylem (Fig. 4) is of diffuse-porous type with a slight tendency to become ring porous. The annular growth rings are quite evident. The solid xylem core is split into numerous radial xylem wedges by the presence of narrow 1-3 cell wide xylem rays. The ray cells can

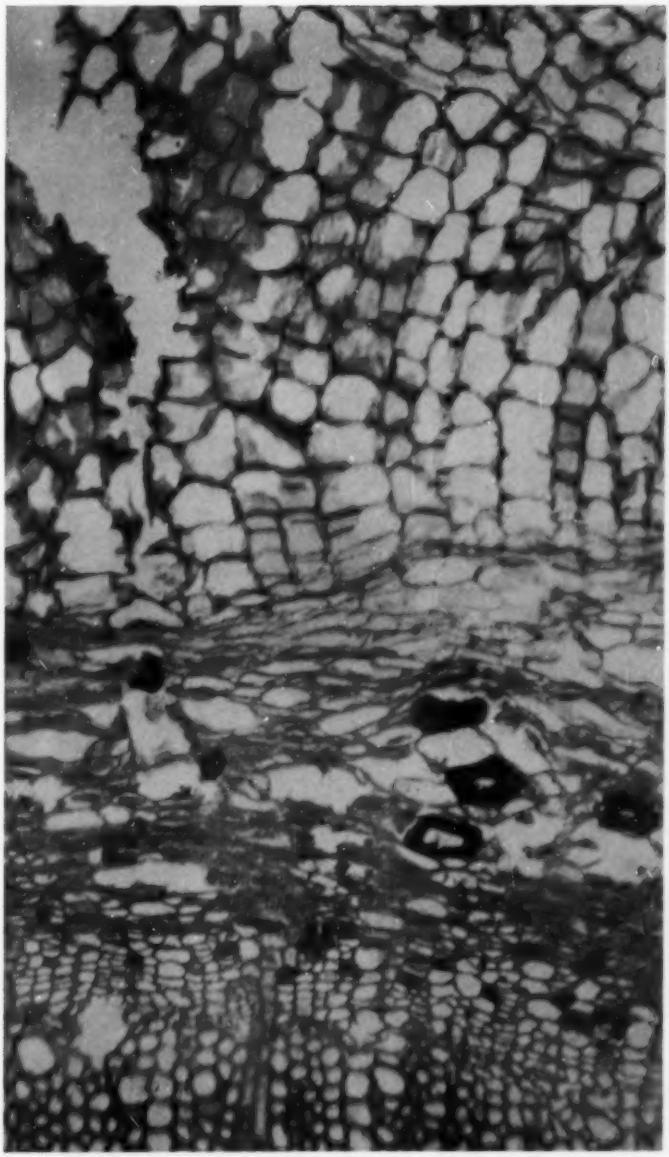

FIGURE 3

Transverse section of a root showing cork with slight evidence of stratification, phellogen, phelloderm, including thick walled fibres, phloem with prism crystals of calcium oxalate, cambium and a part of xylem, × 115.

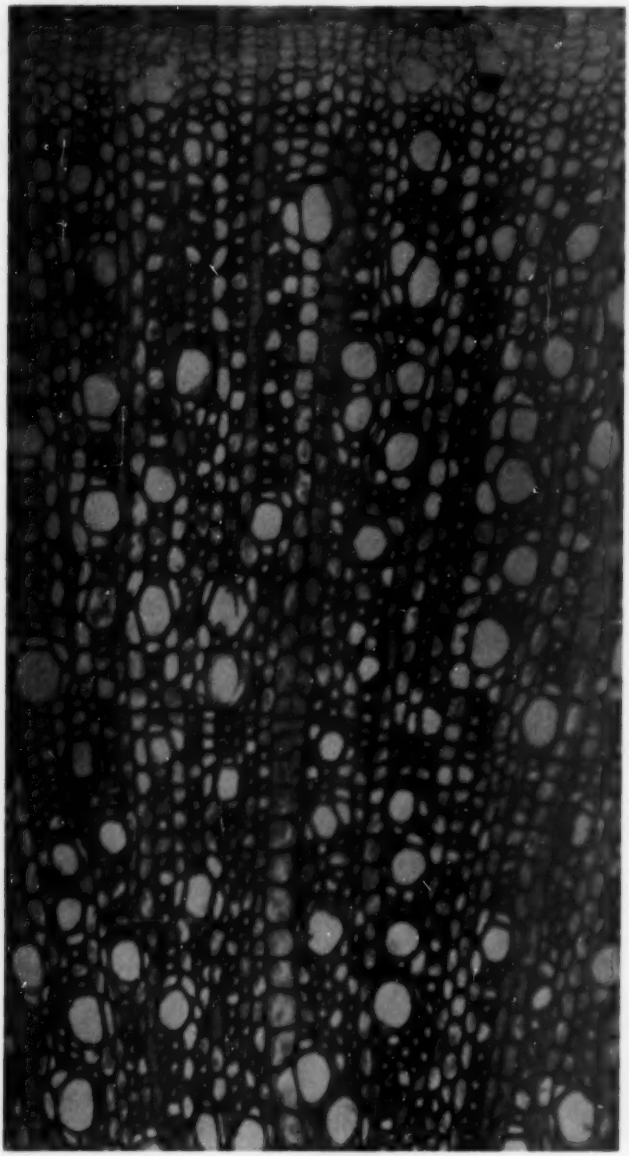

FIGURE 4

Transverse section of a root, showing xylem, annular ring, uni and biseriate medullary rays and scattered trachea, × 110.

FIGURE 5

Photomicrograph of cortical fibers showing different shapes and varying thickness of the wall (from a macerated preparation), × 140.

be distinguished by their radial elongation, porous thickening and heavy starch content. Xylem fibers are numerous in groups. In a macerated preparation (Fig. 7) they appear uniformly thick with pointed or truncate ends. They show characteristic oblique elliptical pores on their walls and measure 950-1450 microns long and 15-22 microns in thickness. Xylem parenchyma is diffuse-in-groups and the cells show pitted walls.

The vessels occur singly or scattered except at the junction of the annular ring where they tend to lie in a concentric circle. They measure 820-1125 microns long and 50-110 microns wide. They show characteristic minute elliptical pits on the walls. The pitting is not uniform over the wall so that certain unpitted or less densely pitted areas can be seen on the wall. The end pores are terminal or lateral, and in the latter case the vessel shows a drawn out pointed end.

FIGURE 6
Cortical fibers from a macerated preparation, × 115.

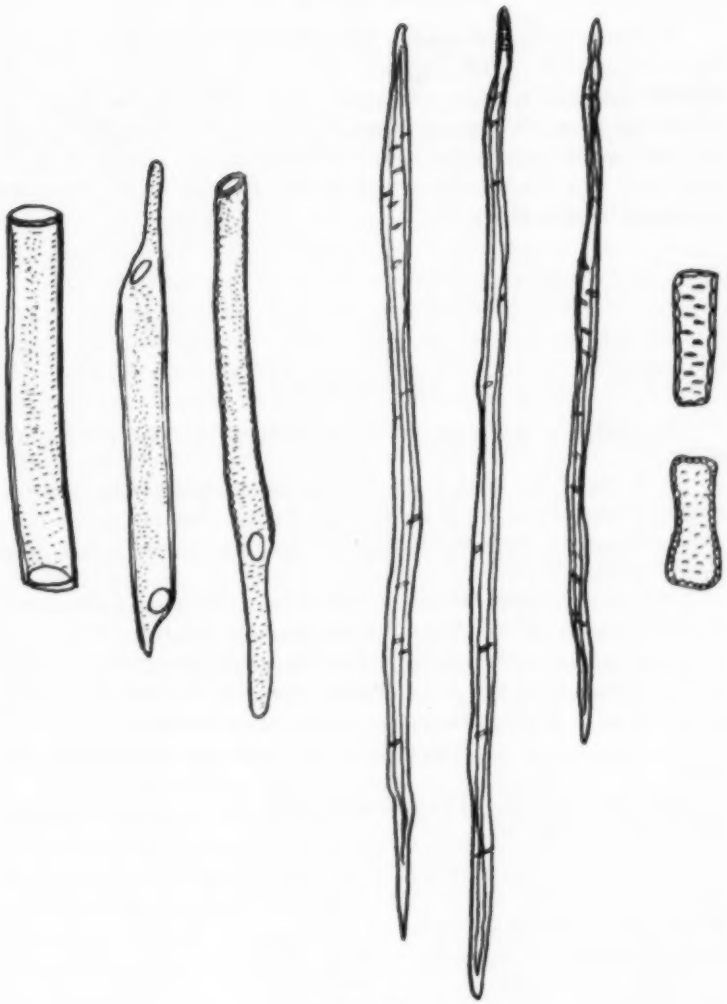

FIGURE 7

Macerated preparation of wood showing pitted trachea, fibers with oblique pores and porous xylem parenchyma cells, × 130.

## Conclusion

*R. decurva* roots are readily distinguished from the roots of other Rauwolfia species. Histologically, they more nearly resemble *R. densiflora*, as described by Youngken (6). The greater length of the cortical fibers, the absence of smaller stone cells in the phloem, and the scattered trachea in the xylem differentiate the species from *R. densiflora*. Examination of two authentic samples of *R. densiflora* confirmed these findings.

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# LOOK IN THE MIRROR *

By W. Paul Briggs **

LOOK in the mirror. Are you really satisfied with the reflection of yourself as a representative of the profession of pharmacy? Would you hire the man you see? Are you unhappy about the view? Do you see the image of a frustrated man?

Or are you looking at a man possessed of self-respect, objectivity and determination? Do you reflect pharmacy as you want it to be?

Mirrors may sometimes be cruel, but they are not false. If we are not satisfied with our own pharmaceutical image how can we hope to gain the praise of others? Happily, mirrors can only reflect—if we change, the image changes. If our pharmaceutical posture can be perfected, the public will see our image as we would wish it.

But beware of thoughts of fooling the mirror of public opinion. The image in that mirror is a true and full likeness, that will reveal the slightest attempt at deception.

What is in the mirror? Sometimes we see an image so blurred that only a psychiatrist could unscramble the reflection. At times, pharmacy may appear as a raucous merchandise mart, and then change while we look, to the image of a dignified, essential public health service. And some very deep mirrors will show the impressive scientific, educational, research and production facilities that are parts of the body pharmaceutic. But the reflections do not hold steady. If we are unsure of how we look to ourselves, how much more confusing must our mirror reflection be to the public?

It is said that no man is really well-dressed until he smiles. Pharmacy will never be well-content with its place in the American scene until the public smiles upon its true professional image. You and I must reflect that image—no trick mirror can do it for us.

How shall we set about doing this? How did you choose your wife, your car, your home, your suit? You decided what you wanted—then you accepted only the object of your choice. It's as simple as

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* Banquet Address, University of Michigan, ANNUAL PHARMACY LECTURES, October 24, 1956.

** Executive Director, American Foundation for Pharmaceutical Education.

that, and no easier or harder. Remember the advice of George Bernard Shaw—"If you don't get what you want, you will end up wanting what you get."

We are living, indeed we are combatants, in an age of revolutions. Scientific, social, and economic revolutions are daily changing the fixed order of our lives. Some seem to feel these drastic changes are wholly destructive and frequently are directed solely at the practice of pharmacy. But look in a big mirror.

To be sure, the scientific revolution has changed the mechanics of pharmacy. The form, the number, and the nature of prescriptions differ greatly from those of even 25 years ago. You were proud of your use of specialized pharmaceutical skills. At the same time, you must have felt pity for the patient who trustingly depended upon your concoction, that often was much more impressive pharmaceutically than therapeutically. Show me the pharmacist who cannot take greater pride in dispensing penicillin than potassium permanganate; $B_{12}$ than Balsam Peru; tetracycline than Taraxacum Fluidextract; or isoniazid than Lobelia Tincture. How would you measure professional achievement—by personal pill rolling or participation in effective service to the sick? The prescriptions you dispense today are potent and pleasant; often those of yesteryear lacked both qualities.

In the past, when manipulative pharmacy was practiced as a daily art, we carefully secreted our prescription counter in the deepest recesses of the shop. The public could not possibly see the skillful work of the pharmacist. We made sure of that! But now, with open view prescription departments, we are concerned because we have fewer occasions to show our specialized skills to the public.

Let's look at this with clinical candor. I do not believe any sick man is greatly concerned whether his medicine is prepared by his personal pharmacist, or by a reputable manufacturer a thousand miles away. But he does want the results that only effective drugs can produce. And today's drug store is loaded, not only with "what the doctor ordered," but with what the patient needs.

If the physician prescribes medicine, prepared by a manufacturer around the corner or 3,000 miles distant, there is only one way for the patient to get it—from his pharmacist. The patient knows this and he respects your role among the health services. Why don't we teach the public to smile upon the indispensable professional services of pharmacy, and stop tormenting ourselves over who fabricates modern prescriptions drugs?

The current movement to Suburbia has reached revolutionary proportions. In selecting a location for a new drug store we used to stand on a corner and count the people passing by, or check the number of grocery stores within six blocks. Now, we use helicopters and aerial photographs to evaluate the area before locating a drug store. Does this seem unbecoming for an ancient and honorable calling? Physicians are using the same modern technics in selecting sites for their offices and clinics. Certainly these are new methods for both, but are they really any less proper?

When people finally get home in the evening to enjoy the dubious blessings of Suburbia, they will not come back to the city for their home and happiness needs—or their health needs either. So the modern suburban drug store supplies these community services. When this is done with discretion and dignity, it need not lower the status of the professional services rendered.

Must we remain bitter and distressed about a trend that cannot be stopped? Why can't we adjust to this change by realizing that everyone and every calling has been affected just as much as pharmacy? Let's make the public smile upon the home and happiness stocks—as well as the vital health services—provided by 20th century pharmacy.

The American economic revolution was fast and furious. It is still shaking the very foundations of our society. Scientific marketing has become an essential tool for all business. It is beamed to the conditions of modern living and the lowering of service costs. Starting years ago with the food cafeteria, and moving on to banking by mail; medical clinics; TV political campaigns; precut meats; and self-service gas stations; marketing of products and services, has been aiming at speed and lower operating costs.

I have a 1955 model car. It's beautiful and powerful, and I am in love with it. But I wish it had a running board, and tires I could change myself if need be. For sometime I kept hoping Chrysler Corporation would put these comfortable, old-fashioned features back on their cars. I now know this will never happen. So I am trying to adjust to all the new features that are probably to my advantage, even though I still think I would like a running board. I am not a defeatist, but I do not believe we can reverse strong trends.

We need not like modern developments to concede their impact, and what is more important, to recognize acceptance by the public. Of course I am unhappy when I am told that in carefully tested drug

stores, prescription volume actually increased after installation of self-service. I would rather not believe this. I am disturbed that the public does not show strong preference for the "old-fashioned" drug store, like the one I once owned. But I am ready to admit that many modern prescription departments emphasize a professional atomosphere that was often lacking in our older stores.

With the exciting growth of professional pharmacies, but concurrent development of merchandising drug stores, some fear a cleavage in the ranks of pharmacy. While these two movements will probably continue in their present directions, the public will not view pharmacy as a "two-level" profession on the basis of physicial facilities and environmental factors.

In some of the largest, excessively commercial drug stores will be found some of the most professionally impressive prescription departments. Perhaps the very intensity of the merchandising effort in these stores has led to the necessity for dramatizing the prescription department.

Public opinion of the basic values of the profession of pharmacy is the collective reflection of many individual experiences. To paraphrase an advertising axiom—all public relations are local. Where the bearing of the pharmacist and the stature of the prescription department, wherever located, reflect the inherent dignity and essentiality of the profession, the public will give its applause and appreciation.

I am not blessing the spread of "super drug stores" and self-service. Neither do I think the exclusive prescription shop is the only "right way" for pharmacy. But I have come to recognize that "viewing with alarm" and sermons from our prophets, will not stop the inexorable economic, social and scientific revolutions, or lessen their impact upon the practice of pharmacy.

Pharmacists are justifiably jealous of their professional place in the scheme of things. To some extent we "are our brother's keeper," but do not forget that our brother pharmacist is very much interested in keeping himself. But they do need professional stimulation and critical self-analysis. The Annual Pharmacy Lectures of the University of Michigan should provide this stimulation and a basis for pharmaceutical reassurance.

Your associations have been active in creating better public appreciation for pharmacy, and plans are now developing for a major public relations program for all of pharmacy. We can anticipate

impressive results from these efforts, but, in the final analysis, you must speak for yourself by word and deed. Public opinion really means your own public—your local public—the people who see and know *you!*

The public rates pharmacy higher than pharmacists themselves. This is the result of individual evaluations—of local reflections. The individuals giving a good rating to pharmacy reflect opinions of pleasant daily experiences at their local level. This is where we all live—locally! The pharmacists of Oregon do not shape public opinion of pharmacy in Michigan. But your pharmacy does shape public opinion in your community. You control the opinion of your own special public.

It would be most presumptuous of me to attempt to detail to you how to operate your pharmacy and conduct yourself as a professional man. You and your brother pharmacists know what must be done. But I do urge you to remember the lessons of your college days and to adhere to the principles of professional ethics. I hope "looking in the mirror" will help all pharmacists to get on with the job.

If we believe in ourselves; if we reflect the kind of man we want others to see; if we stop accepting the judgments we get, and earn the evaluation we want; then we will enjoy the rightful pride of being a pharmacist.

Look in the mirror—and make your pharmacy, in your own community, what it should be. Then stop worrying about public opinion of your profession—you can make it for *your* public! But remember the image you see—the opinion you hear—will be your own reflection. If you really like your own reflection, you can be sure the public also will like it.

# IT IS TIME FOR A LEGISLATIVE CHANGE *

By Robert E. Abrams **

THERE is probably only one word to adequately describe the present day legal atmosphere which now faces the pharmacist and that word is "chaotic". No profession, for that matter, no field of human endeavor, is so over-regulated and legally restricted as is the practice of pharmacy. In fact, it has been stated that the term "practice of pharmacy" has almost become a misnomer. For it now appears that the pharmacist doesn't really practice his profession, he simply complies with the law.

Our legislative history is replete with examples of where legislatures, both State and Federal, in attempting to alleviate a particular problem have drawn up legislation which is completely impractical and necessitates wide deviation either from the law or from good professional practice. The substitution of rules prescribed by the professionally untrained for sound professional judgment, is the natural result of over-regulation. The moral and ethical responsibilities seem to have been completely discounted when pharmacy laws were written. The pharmacist should be, and even must be, in a position to provide advice and guidance, referring the individual to the best particular course for his illness or problem. The pharmacist's training has so provided. His choice of action or his advice should not hinge upon the fear of reprisal at the hands of some punitive body but on his soundness of professional judgment.

A true profession is one that is self regulating and sets up its own code of ethics which it strictly enforces. Pharmacy as a profession has been deprived of this prerogative due to a long history of legislative action based on limited thought and misguided judgment. If we trace the history of most pharmacy legislation we find all sorts of skeletons imagined by the legislatures. Skeletons which never really existed and never could develop. It is not implied that pharmacy is so "simon pure" that some areas do not require some administrative guideposts, however, it is maintained that over the past years pharmacy has changed tremendously but the laws governing the profession, with one notable exception, have not changed with this progress. If anything, they have become more confused and like

* Presented before the Midyear Conference of the A. C. A. Dallas, Texas, Oct. 22-23.

** Executive Secretary, American College of Apothecaries.

Topsy, they have grown without any planning or soundness of judgment. This "chaotic" system which is currently plaguing our professional household can only be attributed to a lack of co-ordinated integrated and concerted legislative action on both the Federal and State level. If our laws are unsound, then we have only ourselves to blame. In most cases the type of action so necessary to inform the legislatures of the role of our profession has been completely lacking. Only in the field of Fair Trade have we offered the type of program which should be effective but this transcends our profession and involves economic factors which are applied to other endeavors as well. It is not the intention to belittle the work done on Fair Trade, for it truly has been outstanding, but this is just one facet of a many faceted problem and even it too, now faces a most trying time.

A study of both our Federal and State laws will reveal that many of the statutes on our books have such breadth and scope that they place the pharmacists in a position where they must act in a manner which is technically criminal if they are to practice their profession in a normal and reasonable manner. It certainly took a long time to have the so-called "oral codeine law" passed but yet pharmacists for years have been accepting narcotic prescriptions over the telephone despite repeated warnings that this practice was illegal. Yet, these pharmacists were acting in complete good faith, thus indicating a single instance where impractical legislative restrictions were placed on our profession.

The above is just a single example of the type problems that are facing us but before we can properly understand these problems we should at least attempt to examine the background that leads up to our present day system of laws and regulations. In this entire history, the one predominant characteristic has been the lack of the profession to exercise self regulation. When this occurs, the government usually steps in and since there was a general disorganized, apathetic attitude (and we are being charitable) the obvious resulted. James Keller warned in his book *Government Is Your Business,* "If the individual disdains a voice in his government affairs, the government will certainly exercise a greater voice in the individual's affairs." He probably was thinking of pharmacy at the time.

The first laws governing pharmacy were developed at the time when the government functioned almost entirely in a negative role with prohibition of specific items the only concern. There were few if any Boards or Agencies at first. The next development was the

creation of Boards of Pharmacy which were probably the first administrative agencies. However, they were forced to carry with them many of the negative laws as holdovers. Then came the establishment of other administrative agencies, the purpose of which was to add flexibility to the written law, providing these agencies with broad rule-making powers and even judicial authority. However, these agencies were initially hampered by the so-called delegation of authority problem but as the people demanded a much more positive approach from government, these agencies with their powers came into full bloom. Certain liberal and yet protective ground rules were laid down for these agencies. It is interesting to note that they were mainly established by more liberal interpretation of the law, which in most cases occurred on the Federal level rather than on the State level. In addition, most Federal agencies exist or operate under more recent laws while those statutes establishing Boards of Pharmacy were established in an era when governmental authority was strictly limited. It is quite obvious that unless State laws and State Boards are brought up to date, more and more regulations in the health field will lie in Washington. One wonders whether it is not now too late for the States to recoup authority which is rightfully theirs.

Mr. Frank Duckworth in addressing the teachers of Pharmacy Administration summed up very lucidly the important facts concerning our current problems of law enforcement by agencies, Federal or State:

> "1. Administrators must not be dominated by those who appoint them. Their sole concern should be the facts and the law, and their decisions should specify the reasons for their conclusions.
>
> 2. Agencies must be staffed with adequate personnel who are paid amounts commensurate with their skills and responsibilities. It has been wisely said, 'Good men can produce better results with a poor law than poor men can produce with a good law.'"

Though we are quick to criticize government for its excesses and failures we have done little to remedy the situation. Many times we blame the agency for its administration when in reality it is the basic law which is at fault and the agency is simply enforcing that law. This was brought to my attention most vividly at the recent Hydro-

cortisone hearings at which we were privileged to testify. The hearings which were conducted with absolute fairness, allowed everyone to be heard and opinions given with respect to the proposal to change these products to the over-the-counter status. The Food and Drug Administration are bound by the law to insist on such over-the-counter sale if the drugs can be proven safe under the labeled directions for use. The law gives little leeway and its interpretation must be based on fact. These restrictions placed on the agency are relatively unsound for when the Food and Drug Administration was established its primary purpose was to safeguard public health. If need be, the public must be protected even against itself and yet the agency is not permitted to exercise any judgment along this direction under the strict legal interpretation of the law. The responsibility of the Food and Drug Administration, at least in our opinion, transcends the cut and dried definition of safety under labeled directions. They should be convinced that common abuses of these directions would not cause injury and yet they are not given this prerogative. Some will say that they should not have this additional authority and there is too much Federal control. They may be right but yet as long as the agency exists it should be operated toward the purpose for which it was initially intended. If the sales of these items were left to professional discretion, that might be different, but once such products are released, the ballyhoo of our modern advertising media takes over and little regard for warnings, etc., is exhibited. In this field many unscrupulous manufacturers have taken advantage of the divided responsibility of the Food and Drug Administration, who controls safety and directions for use and the Federal Trade Commission, characterized by slow drawn out procedures, who control the advertising of such products. Pharmacy and other interested groups must assume a great deal of responsibility for allowing this schism to exist.

There are so many laws affecting Pharmacy that it would be impossible to discuss all of them now and analyze each. It is very obvious that what must be done on both the Federal and State level is to weed out the useless and confusing laws, analyze the remainder, making certain they are sound, and then vigorously enforce them. Let us take just two laws and analyze them. One deals with the professional aspect of Pharmacy while the other, the commercial or economic. No attempt will be made at complete investigation but they should serve as an indication of the existing problems.

First, the Federal Food, Drug and Cosmetic Act. Originally this was enacted with the manufacturer in mind. However, even before the passage of the Durham-Humphrey Amendment, a considerable portion of all enforcement activities were directed toward the retail pharmacist. Yet just read the law and it will become quite obvious that it is virtually impossible for the pharmacist to operate his pharmacy without violating every day, in some manner or means, this statute. Then came the Durham-Humphrey Amendment which for all practical purposes was supposedly designed with the retailer in mind but yet it goes so far beyond the bounds of necessity that it essentially places the pharmacist in a professional strait-jacket. It is alarming to see the increase in the number of pharmacists who are being cited for so-called illegal refills and to realize how many have not as yet been cited but who may be acting in a similar manner. One can not condone these so-called illegal acts for the law is in existence but yet one must wonder whether philosophically this one particular aspect of the law must be wrong. If this is the case, and we do believe it is, some change in the basic law is necessary. Yet many State laws are similarly patterned and contain inaccuracies, overstated prohibitions and in some cases unintelligible language. Furthermore, enforcement has lagged so far behind the law that the legitimate operator is being placed in a serious competitive disadvantage by the few unscrupulous who know the laws will not be enforced and operate with that thought in mind.

To turn to the business end, we come to a law which supposedly was designed to protect the small independent entrepreneur, such as the pharmacist, namely the Robinson-Patman Act. However, today the rank, untouched violations that go on in our industry are so numerous that they could keep a staff of lawyers busy continually. Let us just cite a few examples. It is in violation of the Act to offer special deals, discounts and other consideration to one customer in the same level of distribution and competition and not offer it to all. However, many manufacturers have special accounts and prices supposedly unbeknown to other pharmacists and yet no effort is made to correct the practice. Other manufacturers do not treat all accounts equally in that they will sell all items to say a surgical supply house and not sell all the same items to the retail pharmacist. Special sizes, prices, etc., are quite common to so-called clinics and yet these same things are not available to all on the same basis. We even maintain

that it is in violation of the Robinson-Patman Act for a manufacturer to sell to a physician if that physician in turn charges for the medication. Yet enforcement on these points has been non-existent. Probably because they do not make headlines yet such suits could be forced by individuals or associations if they were so inclined. The violations are obvious, all that is needed is the courage and foresight to correct them.

We have not mentioned the restrictive sales battle in the various States for this in itself can take up an entire discussion. The only comment we make is that there should be no compromise with public health. The protections that the pharmacist offers the public in the sale of proprietary remedies are real and the public is entitled to that protection. If the proprietary interests have the public welfare in mind as they profess, then there is no conflict. All common sense dictates that these items, irrespective of labeling, should be sold under proper professional supervision for the best interest of public health. Thus why the conflict? If however, the proprietary interests have other motives then these should be exposed in the proper manner to the State legislatures and then allow them to make the decision as to what is best in the public interest. A body of facts can be accumulated that would leave no doubts.

If this presentation has been garbled and confused it is because our current legislative situation is in just that state. It can and must be corrected but this can only be done by the intelligent use of good legal talent. A strong leadership is needed to rectify both the professional and economic shortcomings of our present laws. We must insist on an intelligent set of laws with intelligent interpretation by people who are well qualified. No other set of circumstances will do.

There is no question that it is time for a legal change and we are convinced that now is the time to start planning and thinking toward effectuating that change for tomorrow we may find ourselves as professional automatons with every action governed by some law. The pharmacists, next to the postmen see more people and speak to more people than anyone else. They have tremendous political potentials but yet due to their disorganized state have wasted many opportunities and have not explored their potential to change and streamline poor legislation. It is also our responsibility to insist on proper enforcement of those laws which are sound. For only if we discharge these responsibilities faithfully are we meeting the responsibilities of our profession.

# A SUGGESTION FOR A U. S. P. TEST FOR OLIVE OIL

By Wallace Dickhart *

A paper read before the Pittsburgh Branch of the American Pharmaceutical Society by L. Alvino on April 11th 1911, was titled, "Comparisons of Olive Oil 1909-1911." It stated in part: "Olive oil, with the exception of almond oil, is the most expensive fixed oil on the market, and is, therefore, subject to adulteration. For this reason I selected the subject for my graduation thesis. A collection of twelve samples of oils from different stores in the city of Pittsburgh was made. To each sample some of the tests given in U. S. P. by Bechi, Maisch, Leffmann and Beam, Marrie and others were applied. After applying the majority of these tests to the samples collected, it was found that only one of the twelve samples could be labeled pure olive oil."

In those days the chief adulterant was cottonseed oil; but today we are confronted with other types of refined vegetable oils which are more difficult to detect, their characteristics being very similar to those of Olive Oil.

All of the above U. S. P. tests for Olive Oil have been discarded by the present Pharmacopeia and replaced by more modern requirements. Nevertheless, with all these carefully selected U. S. P. tests, it is possible that an Olive Oil could be contaminated with a foreign vegetable oil.

In 1936 the writer first observed the possibility of using Phosphotungstic acid for the detection of Sunflowerseed oil in Olive Oil. Since that time many variations of the test have been made, so as to try to produce, if possible, a general U. S. P. test for Olive Oil. Such a test is outlined below.

Three reagents are reequired "A", "B" and "C". Solution "A": Place 0.10 Gm. of Phosphotungstic acid into a 50 ml. volumetric flask. Add 25 ml. of F 30 Alcohol (10% methyl and 90% ethyl alcohol). Shake until clear, then add 25 ml. of anhydrous ethyl ether and mix. Solution "B" is concentrated sulfuric acid. Solution "C" is acetic anhydride.

Place 1 ml. of the oil to be examined into a 150 mm. test tube and add 5 ml. of solution "A" and mix. Place a thermometer in the

* Official chemist for the Olive Oil Association of America.

test tube and reduce the temperature to 25° C. by placing the tube into a beaker of water at 25° C. Now slowly add (at the rate of 1 ml. per 30 seconds) 1 cc. of concentrated sulfuric acid. When done remove the tube from the water bath and stir with the thermometer and observe the temperature. After it has reached 50-55° C. place the test tube under running water, stirring with the thermometer until the temperature has been lowered at 20° C. Now remove the thermometer and place the tube back into the water bath at 20° C. Slowly layer on the surface (at the rate of 0.10 ml. per 5 seconds) 1.5 cc. of Acetic anhydride. Remove the test tube from the water bath and very slowly rotate the mixture. A ring will form and the acid layer will finally turn color. Under these conditions, U. S. P. Olive Oil should not produce a colored ring nor any color to the acid layer.

Vegetable oils examined by the above method gave the following color reactions.

| | *Color ring* | *Color acid layer* |
|---|---|---|
| U. S. P. Olive Oil | None | None |
| Rice bran oil (refined) | Deep blue green | Deep blue green |
| Corn oil (refined) | Olive green | Olive green |
| Soya bean oil (refined) | Pale green | Pale green |
| Sunflowerseed oil (refined) | Pale green | Pale green |
| Teaseed oil (refined) | Pale green | Pale green |
| Sesame oil (refined) | Dark green | Dark green |
| Rapeseed oil (refined) | Lemon | Lemon |
| Patawa oil (refined) | Red | Reddish brown |
| Almond oil U. S. P. | Chocolate | Brown |
| Peanut oil | Brown | Brown |
| Grapeseed oil | Light brown | Light brown |
| Cottonseed oil | Light brown | Light brown |
| Kapock oil | Light brown | Light brown |
| Palm oil | Greenish brown | Greenish brown |
| Palm Kernel oil | Pink | Light brown |

# SELECTED ABSTRACTS

**A Comparison of the Absorption of Sulfapyrimidines.** Boger, W. P., Strickland, S. C., and Gylfe, J. *Antibiot. Med. & Clin. Therapy 3*:43 (1956). The authors administered sulfisoxazole, sulfadimetine and a triple sulfonamide (sulfamerazine, sulfadiazine, and sulfamethazine) to twelve patients. Each received the three sulfonamides in rotation for five days with a 7-day lapse period between. The same schedule of dosage was used for each drug, as follows: 4 Gm. initially then 1 Gm. three times during the rest of the first day, and 1 Gm. four times a day during the remaining four days of the course.

From the results obtained, it was found that the plasma level of sulfisoxazole reached a peak in less than 4 hours and then dropped off to a steady lower level. Sulfadimetine reached a somewhat higher peak plasma level in just a little more time than did sulfisoxazole, then dropped off rapidly to a steady level slightly higher than that of sulfisoxazole. The triple sulfonamides reached a peak plasma level in about 6 to 8 hours. However, this peak level was maintained steady and was about comparable to the peak reached by the other two sulfonamides. It was thus evident that the soluble sulfonamides provided promptly effective therapeutic plasma concentrations but, unless sustained by frequent and large doses, the sulfonamide plasma concentrations were not maintained at a high level. The triple sulfonamide mixture provided a more slowly attained therapeutic plasma level, but on small divided daily doses higher plasma concentrations were maintained than with the soluble sulfonamides. It was pointed out that the plasma levels maintained by 1 Gm. doses of the triple sulfonamide approximated the peak concentrations from 4 Gm. initial doses of the soluble sulfonamides.

Acetylation of the drugs was also compared. It was found that the degree of acetylation of sulfadimetine was quite low. However, the degree of acetylation of sulfisoxazole was slightly greater than that of the triple sulfonamide. The authors noted the possible danger in this since acetylated sulfisoxazole must be excreted by the kidneys and is presented for excretion as a single compound whereas the triple sulfonamides are presented as three compounds each representing about one-third of the total concentration.

**The Suppression of Dental Caries by Pyridoxine.** Strean, L. P., Gilfillan, E. W., and Emerson, G. A. *The N. Y. St. Dent. J. 22:*325 (1956). In this preliminary study, the authors fed ten hamsters a cariogenic diet. One half of the animals received 50 μg. of pyridoxine per 100 Gm. of ration while the other half received 1000 μg. of the vitamin per 100 Gm. of the ration. A 5 per cent sucrose solution was supplied *ad libitum* to all of the animals in place of water. The study lasted for a period of ten months.

A method of scoring was developed to indicate the relative amount of crown structure of the teeth that was destroyed. At the end of the test period it was found that the teeth of the hamsters receiving the suboptimal dosage of pyridoxine showed a 26.1 per cent loss of tooth structure while those receiving an excess of pyridoxine showed a loss of only 4.2 per cent. The suppressive effect of pyridoxine was evident in the teeth of all of the latter group. The hamsters receiving the suboptimal dosage of the vitamin showed wide variation in the extent of tooth decay, ranging from 6.6 to 63.7 per cent. The weights of the animals remained essentially the same in the two groups, thus indicating no essential difference in the nutritional status of the animals.

The authors indicated that, although this was a preliminary study, the results would suggest that the difference in the extent of tooth decay was too much to be coincidental.

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**The Stability of Solutions of Acetylsalicylic Acid in Alcohol.** Wing, W. T. *Pharm. J. 177:*158 (1956). It is well known that acetylsalicylic acid hydrolyzes quite rapidly in aqueous solution. The rate of this hydrolysis greatly increases with heat. However, solution of the acid in water is very slow without the application of heat.

A need exists for a solution of acetylsalicylic acid for intravenous infusion in certain types of emergencies involving severe brain damage. The author prepared a solution of the acid in absolute alcohol so that 1 Gm. was contained in 8 ml. of solution in an ampul. When needed, the contents of the ampul were added to 500 ml. of isotonic sodium chloride solution. The small amount of alcohol was not objectionable.

The stability of this alcoholic solution of acetylsalicylic acid was then studied. Ampuls containing the solution were divided into three groups. Some were unheated, some steamed at 98 C. for 1 hour, and some autoclaved at 115 C. for 30 minutes. By color comparison, the solutions were examined for the free salicylic acid content using the B. P. limit test. The results indicated that the solutions did not decompose when subjected to these heat treatments. To evaluate the effect of small amounts of water in the solution, 10 per cent acetylsalicylic acid was dissolved in absolute alcohol, in absolute alcohol with 0.5 per cent water, and in absolute alcohol with 1 per cent water. Half of the ampuls containing each of these solutions were autoclaved and the rest were stored in an incubator at 37 C. Samples were taken for titration analysis at intervals, the final samples being assayed after 25 months. The results indicated that the loss, after 25 months, in no case was more than 2.5 per cent. There was no significant difference among the solutions. Thus, it would appear that up to 1 per cent water in absolute alcohol permits the preparation of a solution of acetylsalicylic acid which is stable for at least 2 years.

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**Aerosol Hydrocortisone in the Treatment of Chronic Asthma.** Brockbank, W., Brebner, H., and Pengelly, C. D. R. *The Lancet 271:807* (1956). Eighteen patients with chronic asthma were treated in a blind test of the effectiveness of aerosolized hydrocortisone. None of these patients had been controlled by antispasmodics. One-half of the patients were given hydrocortisone hemisuccinate and one-half were given lactose. One hundred milligrams of each powder were dissolved in 2 ml. of a diluent consisting of sterile water, chlorabutanol and a Triton. This constituted a week's supply, to be administered by the patient in doses of about 5 mg. three times a day by means of an inhaler. The total treatment period was ten weeks.

At the end of the trial period, when it was known which patients had received the medication and which had received the placebo, it was found that only one patient of the 9 who received the hydrocortisone had shown marked improvement. Six of these patients had shown no improvement and 2 had shown slight improvement. Of the 9

patients receiving the inert material, 3 were much improved, 2 slightly improved, and 4 had shown no improvement. Improvement was based upon the lessening of attacks in duration and frequency, the lessening of the need for antispasmodic material, and improved health and mobility.

The authors concluded that hydrocortisone by aerosolization was ineffective in the control of chronic asthma.

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**The Preparation of a Satisfactory Freeze-Dried B. C. G. Vaccine.** Ungar, J., Farmer, P., and Muggleton, P. W. *Brit. Med. J.* No. 4992:568 (1956). A method was reported by the authors for the preparation of a satisfactory freeze-dried, viable vaccine from B. C. G. The B. C. G. organisms were grown in deep culture in Sauton's medium containing 1:4000 Triton WR1339. The addition of the wetting agent, selected after tests with a large number of such agents, permitted the deep culture method instead of the traditional surface culture methods. The organisms were harvested by centrifuging and required no milling to produce a homogeneous suspension. The latter was also an advantage gained by the inclusion of the wetting agent in the culture medium.

The harvested organisms were then resuspended in a medium consisting of 8.3 per cent dextran, 1:4000 Triton WR1339, and from 0 to 20 per cent glucose. This suspension was then freeze-dried. The preparation was held at —50° C. for one hour and then freeze-dried at a temperature not above —20° C. during most of the cycle and not above +25° C. during the final stages of drying. The drying cycle required 16 hours. An additional four hours exposure to phosphorus pentoxide was employed as a secondary drying cycle.

Viable cell studies showed that a small amount of water must be retained by the product in order to preserve viability of the cells. The absence of glucose in the suspending medium resulted in a very low moisture content and a complete loss of viability of the cells. Twenty per cent glucose produced a physically unsatisfactory product. The optimum glucose content appeared to be about 7.5 per cent. This concentration of glucose permitted the retention of about 1 per cent moisture. This freeze-dried product was found to be stable to storage for at least twelve months when kept at a temperature of less than 20° C.

The authors also elaborated on a method for enumerating the viable cells to give consistent results. They found that there was a direct relationship between the viable cell count and the size of lesions produced in guinea pigs after intradermal injection. They also showed that the tuberculin conversion of guinea pigs was related to the viable cell count.

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**A Chemical Method for Distinguishing Human-Type Tubercle Bacilli from Other Mycobacteria.** Konno, K. *Science 124*:985 (1956). A previous study had been reported in which it was shown that human-type tubercle bacilli produced markedly more niacin than other mycobacteria when grown on synthetic culture media. The present study indicated the results obtained from the use of a chemical method for detecting the amount of niacin produced by the organisms.

Fifteen strains of standard laboratory mycobacteria, 50 strains of tubercle bacilli obtained from tuberculous patients, including 3 isoniazid resistant, catalase deficient, strains which did not produce progressive tuberculosis in guinea pigs, and 10 strains of atypical acid-fast bacilli, most of which were chromogens, were grown on Lowenstein-Jensen's solid culture media for up to 3 months. A few colonies were removed from the media and transferred into a test tube containing 1 ml. of 4 per cent aniline solution in 96 per cent alcohol. To this was added 1 ml. of 10 per cent cyanogen bromide in water. A positive test was shown by the development of an intense canary-yellow color in the bacterial sediment and, later, in the supernatant fluid. Only the human-type tubercle bacilli, irrespective of virulence, gave a positive test. No difference was noted in the test results between isoniazid sensitive or resistant or between catalase producing or deficient strains. Bovine, avian, nonpathogenic mycobacteria and the atypical acid-fast bacilli did not produce a positive test.

# BOOK REVIEWS

**The Pursuit of Science in Revolutionary America 1735-1789.** By Brooke Hindle, Ph.D., University of North Carolina Press, Chapel Hill, North Carolina.

In this book Dr. Hindle has amassed a tremendous amount of historical information on what might be said to be the beginning of scientific endeavor in America. It is interesting to note the prominence of Physicians in early scientific circles. Naturalists, preachers and teachers too played outstanding parts in the early development of science. The founders of the American Philosophical Society in Philadelphia fostered by such men as Franklin, Rittenhouse and others gave great impetus to scientific achievement.

It is a most interesting story of the history of science and its influence on the War for Independence and the ensuing years.

B. C. GOODHART

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**Steric Effects in Organic Chemistry.** Melvin S. Newman, editor. vii + 710 pp. John Wiley and Sons, Inc. New York 16, N. Y. 1956. $12.50.

Twelve authorities have contributed to the wrting of this book which deals mainly with the steric effects on the reactivity and properties of organic molecules. The thirteen chapters are largely devoted to the influence of non-polar groups on the reactivity of the molecules. The text is primarily intended as a reference work to sift and correlate the great number of recent papers on the treatment of steric factors.

Each chapter is well supplied with references and the literature appears to be covered to the middle of 1955. An author and subject index are also included.

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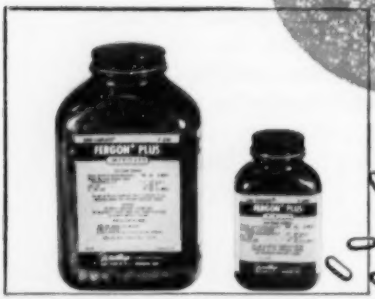


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